UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERCK EPROVA AG,

Plaintiffs,

-vs.- 09 CV 9684

BROOKSTONE PHARMACEUTICALS, LLC
a/k/a ACELLA PHARMACEUTICALS, LLC,

Defendant.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA

SCIELE PHARMA, INC., Case No. 1:09-cv-03283-JEC

Plaintiff,

v.

BROOKSTONE
PHARMACEUTICALS, L.L.C.
a/k/a ACELLA PHARMACEUTICALS, L.L.C.

Defendant.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

PAMLAB, L.L.C., and METABOLITE LABORATORIES, INC., Plaintiffs,	CASE NO. 2:09-cv-07434
v.	SECTION S
BROOKSTONE PHARMACEUTICALS, L.L.C. a/k/a ACELLA PHARMACEUTICALS, L.L.C. Defendant.	MAGISTRATE DIVISION 3

DECLARATION OF BRIAN C. REISETTER, RPh, MB.A, PhD

I, BRIAN C. REISETTER, pursuant to 28 U.S.C. § 1746, declare as follows:

1. My name is Brian C. Reisetter. I am over the age of eighteen and a resident of Oxford, Mississippi and am competent to make this declaration. I have personal knowledge of the facts stated herein.

2. I currently serve as a partner with Medical Marketing Economics, where I perform pricing and marketing research and consultation for the pharmaceutical and medical industries. In addition, I serve as an adjunct faculty member at the University of Mississippi, Department of Pharmacy Administration in Oxford, Mississippi. I am also a licensed pharmacist in the states of Iowa and Mississippi. I have acted as an expert witness in litigation matters involving the marketing and sales of pharmaceuticals and medical devices. My current *curriculum vitae* are attached to this declaration as Appendix A of this report.

3. I am being compensated at the rate of $450 per hour as and expert in this case. My compensation is not contingent upon the outcome of this case.

4. In this matter, I was asked to offer my opinion on the market impact of the claims by Brookstone Pharmaceuticals, LLC (Brookstone) that Folast, PNV-Select, and PNV-DHA contain the identical ingredient, L-methylfolate, as

METANX® by Pamlab, and PRENATE ELITE® and PRENATE DHA® by Sciele respectively.

5. It is my expert opinion that Brookstone's promotional claims that Folast, PNV-Select, and PNV-DHA contain L-methylfolate in the same strengths as METANX®, PRENATE ELITE® and PRENATE DHA® resulted in the market believing these products to be pharmaceutically equivalent. These claims are apparently false because Folast, PNV-Select, and PNV-DHA do not actually contain L-methylfolate. Due to these false claims, the purported "generic" products by Brookstone were electronically "linked" in databases by pricing compendia databases, pharmaceutical wholesalers, pharmacy chains, and individual pharmacies as potential products for substitution at the pharmacy level. As a result, Pamlab and Sciele will suffer irreparable harm in the form of lost market share, price erosion of the market, and good will of the branded products that will impact future sales.

6. As support for this conclusion, it is important to understand the goals of generic pharmaceutical promotion, the industry-wide databases of drugs and drug prices for the industry, and the actual behavior of pharmacies and pharmacists during the dispensing of generic medications as outlined in the following sections.

Goals of Pharmaceutical Promotion

7. Generic pharmaceutical companies have significantly different marketing goals than branded pharmaceutical companies due to the distribution differences outlined below. Branded pharmaceutical companies create demand by marketing to physicians, while generic pharmaceutical companies create demand at the pharmacy level by encouraging substitution of branded products with their generic products.

8. Branded pharmaceutical companies of innovator products attempt to establish how their products are different from the competition, a process that includes the physician. These companies promote their brands directly to physicians. Their entire marketing strategy is centered on establishing their brand identity and working with physicians in finding appropriate patients who would benefit from their unique branded drug. The process of branding a prescription drug is imperative for manufacturers and distributors of sole-source prescription products produced by innovator companies. This process is imperative because physicians build experience with the use of specific products. That experience, if positive, will create loyalty to that specific brand, because physicians know they can trust that prescription product to be a safe and effective treatment for their patients.

9. Conversely, generic companies attempt to establish how their products are equivalent to the competition, a process that predominantly excludes the physician. In this context, the ultimate marketing target is the dispensing pharmacist rather than the physician. The marketing goals for generic companies are twofold: 1) make pharmacists aware that a substitutable product exists, and 2) show pharmacists the profit potential of using their specific generic product over the branded or other generic products. Pharmacists can make some product substitutions without contacting the physician, and generic products are one example of this substitution process.

Role of Industry Databases and Compendium

10. One method that generic manufacturers use to inform the market that their generic products are equivalent to branded products is through industry pricing and database compendia, such as Medi-Span and First DataBank, the two most commonly used industry databases. Because of my work in pharmaceutical marketing, pricing, and sales, I am knowledgeable about drug databases such as First DataBank and Medi-Span. The information in these databases includes the drug's active ingredients, dosage form, strength of active ingredient(s), and route of administration.

11. To simplify generic purchasing and product comparison, these companies have created coding systems for products having the same active ingredient(s). For example, Medi-Span has created Generic Product Identifier (GPI) codes as part of their classification schema. A product will have the same GPI code if it contains 1) the same active ingredients, 2) in the same amounts, 3) in the same dosage form (e.g., capsules, tablets, etc.), 4) for the same route of administration (e.g., oral, topical, etc.). Products matching these four criteria are considered pharmaceutical equivalents[1], which is the basis for this classification schema. Without matching these four criteria, products would not be given the same GPI classification by Medi-Span.

12. First DataBank has a similar classification schema with the same criteria of pharmaceutical equivalents as the basis for the classification of their Generic Code Numbers (GCN). As with GPI codes, products without the same amounts of the same ingredients in the same dosage form for the same route of administration could not receive the same GCN codes.

[1] Pharmaceutical equivalent is a term defined by the Food and Drug Administration (FDA), and can be found in the preface of "The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm, accessed 11/30/09.

13. This grouping of matching products is commonly referred to as "linking." Products that receive the same classification code by a database are said to be "linked."

14. Wholesalers (e.g. Cardinal, McKesson) and pharmacy chains (e.g., Walgreens, Wal-Mart) also link branded products to generic alternatives with the software they use for pharmacy ordering and dispensing purposes based on the GPI or GCN. When pharmacists enter a branded product name in these programs, the generic alternatives are usually listed to assist pharmacists in quick and easy ordering and/or dispensing of appropriate product substitutes.

15. The drug databases such as First DataBank and Medi-Span do not test or assay the products listed in their systems. The databases put drug products into respective classifications based upon the information provided by the drug product's marketer. Typically, this information consists of the drug product's label and package insert. Thus, two drug products that are labeled to contain the same active ingredients, dosage form, strength of active ingredients, and route of administration will receive the same classification and be "linked."

16. Because the drug databases do not test any drug products to verify that label claims are met, it is imperative that the information provided by the drug's marketer (e.g., the label and the product insert), be truthful and accurate. If the

label and product insert are not truthful, a product could get "linked" to another product even though the two products do not have the same active ingredients, dosage form, strength of active ingredients, and/or route of administration.

Linked Products and Pharmacy Distribution

17. The linking of branded products to generic products (and generic products to each other) is an integral factor in the selection of appropriate substitutable products at the pharmacy level. The basic tenet of this process is that pharmacists can be assured that products with the same GPI or GCN codes are at a minimum pharmaceutically equivalent to each other, meaning that they have the same amount of the same active ingredient in the same dosage form for the same route of administration. Pharmaceutical equivalence is the minimal standard for appropriate substitution of products at the pharmacy level of distribution.

18. Reliance on this assumption is ubiquitous at every level of pharmaceutical purchasing and dispensing. Wholesalers subscribe to Medi-Span and First DataBank to make purchasing decisions regarding products. Chain pharmacies use this information to "link" products within their corporate-wide pharmacy dispensing software programs. Insurance companies and health plans use compendium information to make product payment decisions. Individual

pharmacists use this information to make individual product selection decisions for individual prescriptions for their patients.

19. As an example, assume a pharmacist was presented with a prescription for Prozac (fluoxetine). When the pharmacist enters that prescription to be dispensed into the dispensing software system, that software will likely tell the pharmacist that generic fluoxetine products exist for Prozac. Most states allow for the substitution of the generic fluoxetine for the branded Prozac without first contacting the prescribing physician for approval. The information used with these pharmacy computers is based on "linking" codes such as GPI or GCN.

20. If the pharmacist needs to order more generic fluoxetine, they will rely on the wholesaler ordering software to make purchasing decisions. The branded Prozac plus the numerous generic fluoxetine products by multiple manufacturers will also be "linked" to each other within that wholesaler software based on those GPI or GCN codes.

21. Additionally, any third party payer (insurance company or health plan) will base the appropriateness of reimbursement decisions on the similarity between the product prescribed and the product dispensed. Again, those decisions are based on the GPI and GCN coding schema.

Individual Pharmacist Label Comparisons

22. Another mechanism available to dispensing pharmacists to make product selection decisions is to actually compare the physical labels or product inserts of the products. As mentioned, the bare minimum for appropriate product substitution is pharmaceutical equivalence, meaning products have the same active ingredients, dosage form, strength of active ingredients, and route of administration. Upon physical inspection, pharmacists can commonly determine that products are of the same dosage form (tablets vs. capsules) and route of administration (oral vs. topical).

23. However, pharmacists must rely on the information provided by the manufacturer on the label or package insert itself to determine if the products contain the same amounts of the same active ingredients. If the information provided by the manufacturer is not accurate, inappropriate product selection can easily occur, resulting in patients receiving a product not intended for them by either their physicians or pharmacists.

Generic Pharmaceutical Promotion

24. Manufacturers of generic pharmaceutical products are fully aware of the importance of "linking" within databases such as those available through Medi-Span and First DataBank. Without being linked within these databases, the

products would not likely be considered equivalent and substitutable by wholesalers, health and insurance payers, corporate pharmacies, or individual pharmacists. As such, manufacturers of generic companies routinely develop strategies to ensure linking within these systems as part of their overall marketing plans.

25. As mentioned, Medi-Span and First DataBank do not test products to make these linking determinations, but instead rely solely on information provided to them by the manufacturers of the products being considered. Information provided and relied upon primarily includes 1) the package insert and 2) the physical labels of the products being considered. False information in the labeling and promotion of products therefore results in inappropriate linking at the database compendium level that has deleterious downstream effects.

26. Pamlab, LLC is a brand drug company based out of Covington, LA that markets a product called METANX®. METANX® is an orally administered prescription medical food for the dietary management of endothelial dysfunction in patients with diabetic peripheral neuropathy. METANX® is labeled to contain 1) L-methylfolate 2.8mg, 2) pyridoxal 5'-phosphate 25mg, and 3) methylcobalamin 2mg as the active ingredients. METANX® is available by prescription only. ***See Appendix B (METANX® Package Insert).***

27. Sciele is a brand drug company based out of Atlanta, GA. Sciele markets two prescription prenatal vitamin products called PRENATE ELITE® and PRENATE DHA®. These products each contain a different combination of vitamins and minerals, but both products are labeled to contain "L-methylfolate as Metafolin® 600 mcg" as one of those active ingredients. PRENATE ELITE® and PRENATE DHA® are prescription medications available only through physician prescribing. ***See Appendix C (PRENATE ELITE® and PRENATE DHA® Package Inserts).***

28. METANX®, PRENATE ELITE® and PRENATE DHA® each contain the active ingredient L-methylfolate [6(S)-5-MTHF] also known by its trade name, Metafolin®. Metafolin® was developed and is manufactured and sold by Merck KGaA. L-methylfolate is the natural, active form of folate, which is necessary for red blood cell formation and DNA and RNA synthesis in the body.

29. Metafolin® is integral to the unique value messages for both Pamlab and Sciele in the marketing of their products, which contributes to the overall branding and brand equity of their products and the value of those assets.

30. Brookstone Pharmaceuticals is a generic pharmaceutical company. Brookstone markets and sells a product called Folast that is promoted in its labeling and product information as a purported "generic" to Pamlab's product

METANX®, including L-methylfolate 2.8mg. Folast is promoted as a "generic" version of METANX®, and appears from the labeling and promotional materials to be a pharmaceutically equivalent product, containing the same amount of the same active ingredients in the same dosage form for the same route of administration as METANX®. ***See Appendix D (Folast Package Insert).***

31. Brookstone also markets and sells products that are promoted in their labeling and product information as purported "generic" versions of Sciele's PRENATE ELITE® and PRENATE DHA®. These Brookstone products are PNV-Select and PNV-DHA respectively. For example, PNV-DHA is labeled to contain the same amount of all active ingredients as the branded product PRENATE DHA®, including 600mcg of L-methylfolate, as Xolafin™.[2] ***See Appendix E (PNV-DHA Package Insert).***

32. Because the Brookstone's products are labeled as containing the identical active ingredients, strengths, dosage forms and routes of administration as METANX®, PRENATE ELITE® and PRENATE DHA®, First DataBank and Medi-Span have "linked" Brookstone's products to METANX®, PRENATE ELITE® and PRENATE DHA®. The products have received the same GPI and GCN codes from Medi-Span and First DataBank respectively. As such, these

[2] Xolafin™ is a trademark of Brookstone Pharmaceuticals.

"generic" products are linked within the pricing compendium, wholesaler databases, and pharmacy dispensing software systems. ***See Appendix F (Screen Shots of Medi-Span and First DataBank linking).***

33. According to information I have been provided, Brookstone's products, however, do not actually contain the same active ingredients in the same strengths as METANX® PRENATE ELITE® and PRENATE DHA®. Specifically, although the Brookstone products are promoted in their labels and product information as containing L-methyfolate, in fact they contain D,L-methylfolate [D,L-5-MTHF], the racemic form of methylfolate. D,L-methylfolate is a materially different active ingredient from D,L-methylfolate, because it contains both isomers of methylfolate, D-methylfolate and L-methylfolate, each with differing activity in the human body. ***See e.g., Expert report of Jesse F. Gregory, Ph.D.***

34. It is commonly known by pharmacists that different isomers of the same molecular formula have different activities in the body. The most common example of the differing physiological activity of different isomers is that of quinine and quinidine. Quinine is a pharmacological agent approved in the US as an antimalarial drug. Quinidine, a stereoisomer of quinine, is a pharmacological agent approved in the US as an antiarrythmic for the heart. Although these

products have the same molecular formula, their activity within the human body is quite different, and confusing the two agents could prove dangerous or even fatal.

35. Additionally, testing demonstrates that the Brookstone's purported "generic" for METANX® – which is also promoted as containing 25mg of pyridoxal 5'-phosphate (the amount in METANX®) actually contains less than two-thirds of the labeled amount of that agent. ***See Appendix G.***

36. If these Brookstone products do not contain the labeled amounts of L-methylfolate or pyridoxal 5'-phosphate, or contain the racemic mixture of D,L-methylfolate rather than L-methylfolate alone, then these products could not be considered as pharmaceutical equivalents to the brand products and thus could not be considered for generic substitution.

Market Impact of Improperly Labeled Brookstone Products

37. The market affects of such improperly labeled products are numerous. These purported "generic" products, because they are "linked" through the same GPI and GCN coding, will lead pharmacists and other pharmacy purchasers (e.g., chain pharmacies, wholesalers) to improperly believe that these products are pharmaceutical equivalents. As such, pharmacists could improperly choose one of these Brookstone products to be dispensed instead of the branded products they purport to mimic. The result would be patients receiving the wrong

medication intended by both the prescribing physician and by the dispensing pharmacist.

38. In my previous research, this linking along with manufacturers representing their products as "generic" products when they are not classified by the FDA as A-rated generics by definition, will result in improper substitution at the pharmacy level. It is not uncommon for branded products to lose 60% to 90% of product sales within the first year after a generic product becomes available.[3]

39. This improperly garnished market share can have lasting effects. The most direct effect will be on the sales of the branded products, which will be diminished from improper substitution. In addition, these purported "generics" can put price pressures on the market, forcing down the acceptable price ranges for the entire classification of products. All three Brookstone products (Folast, PNV-Select, and PNV-DHA) entered the market at significantly lower prices than their branded counterparts.

40. Of particular concern regarding price erosion is within the insurance plans or health plans that pay for a significant portion of these products. Most third-party prescription coverage plans allow generics to be dispensed to patients at

[3] See FTC report entitled "Follow-on Biologic Drug Competition," (2009), pg13 at http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf accessed 11/30/2009.

a lower cost to the patient, referred to as the patient copayment or out-of-pocket (OOP) expense.

41. For example, generic products are often dispensed to patients with a patient copayment of approximately $10. Branded products are often dispensed with a higher copayment amount of anywhere from $25 to $60 per prescription. When generic alternatives exist, branded products are often moved from lower copayment levels or tiers (e.g., $25 to $30) to higher copayment levers or tiers (e.g., $35 to $60) to encourage patients to use the available generic alternatives.

42. The existence of purported "generic" products by Brookstone within these markets, therefore, can result in higher patient copayment amounts for patients than would exist if Brookstone had accurately labeled its products. As such, these purported generic products will further detrimentally affect the market share of the Sciele and Pamlab products.

43. Additionally, because the Brookstone products are not actually equivalent to METANX®, PRENATE ELITE® and PRENATE DHA® and have not been clinically tested, they cannot be expected to provide the same health benefits to the patient. Besides the obvious differences in patient benefit and potential outcomes, such differences between branded products and purported "generics" can have detrimental market effects.

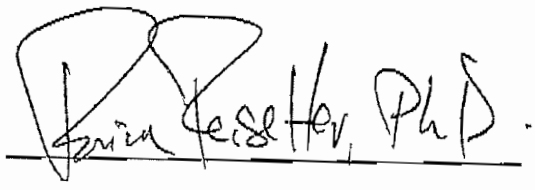
44. Such automatic substitution of "generic" products often occurs without the physician even being aware that the branded product was not dispensed, but was substituted with another product. As such, any resulting effects of the dispensed products will be assumed to be a result of the branded agent prescribed. If the patient does not respond to the product as expected, it will be assumed that the branded product did not perform as it should have, which would permanently tarnish the reputation of the branded product. As a result, physicians may stop prescribing that branded product, which could lead to the inadequate treatment of a patient in addition to the financial loss incurred by the manufacturer of the prescribed branded product.

45. As a result of these findings, it is my expert opinion that Pamlab and Sciele will suffer irreparable harm in the form of lost market share, price erosion of the market, and good will of the branded products that will impact future sales.

Pursuant to 28 U.S.C. § 1746, I, Brian Reisetter, certify under penalty of perjury that the foregoing is true and correct.

December 1 / 2009

Dated



Signature